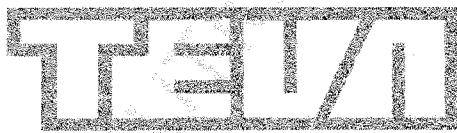


PSJ17 Exh 122



**Document Number:** SOP-8280

**Document Title:** SUSPICIOUS ORDER MONITORING - CUSTOMER SITE  
VISITS



TEVA PHARMACEUTICALS USA

**Revision Number:** 01

**Vault:** PA SOPS

**Effective Date:** 18 Jun 2018

## Signature Manifest

Document Number: SOP-8280

Revision: 01

Title: SUSPICIOUS ORDER MONITORING - CUSTOMER SITE VISITS

SOPDEAMULTI1-FEB2018-JR-0

### DC Preview

Name/Signature	Title	Date	Meaning/Reason
JAMIE L. RAMOS (JI RAMOS)		12 Feb 2018, 10:24:15 AM	Approved

### Requestor/Author

Name/Signature	Title	Date	Meaning/Reason
KELLEY SHAW (KSHAW02)		15 Feb 2018, 10:44:22 AM	Approved

### Cumulative Mgmt

Name/Signature	Title	Date	Meaning/Reason
COLLEEN MCGINN (CMCGINN)		19 Feb 2018, 03:06:22 PM	Approved
VALERIE HAMMING (VHAMMING)		22 Feb 2018, 09:36:40 AM	Approved

### DC Release

Name/Signature	Title	Date	Meaning/Reason
JAMIE L. RAMOS (JLRAMOS)		07 Jun 2018, 02:15:38 PM	Approved

SOP #:	<b>SOP- 8280</b>
TITLE:	SUSPICIOUS ORDER MONITORING – CUSTOMER SITE VISITS

1. PURPOSE

To establish a procedure to obtain information via onsite visits, about new and existing customers who order controlled substances to determine their level of compliance with DEA regulations.

2. SCOPE

DEA Compliance personnel will be responsible for conducting onsite due diligence investigations on new and existing accounts.

3. SUMMARY OF REVISIONS

1. Biennial Review – No Changes

4. REFERENCES

“Know Your Customer Policy”

“It is fundamental for sound operations that handlers take reasonable measures to identify their customers, understand the normal and expected transactions typically conducted by those customers, and, consequently, identify those transactions conducted by their customers that are suspicious in nature.”

[http://www.deadiversion.usdoj.gov/chem\\_prog/susp.htm#cla](http://www.deadiversion.usdoj.gov/chem_prog/susp.htm#cla)

5. DEFINITIONS

**DEA:** Abbreviation for the Drug Enforcement Administration

**SOM:** Abbreviation for Suspicious Order Monitoring

**SUSPICIOUS ORDERS:** Includes but not limited to orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”

**DNS:** Abbreviation for the Do Not Ship List.

**ANNOUNCED SITE VISITS:** Customer site visits that have been scheduled with the customer. The customer is aware of the visit and has agreed to the visit.

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TITLE:	SUSPICIOUS ORDER MONITORING – CUSTOMER SITE VISITS

**UNANNOUNCED SITE VISITS:** Site visits that are primarily covert in nature. The customer may be unaware of the visit, and the visit may or may not include direct contact with the customer or customer's employees.

## 6. PROCEDURE

<u>Responsibility</u>	<u>Action</u>
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6.1 Customer Site Visits

**DEA Compliance**

6.1.1 At the direction of DEA Compliance Management, direct communication may be warranted between TEVA and the customer SOM Subject Matter Experts, up to and including a site visit in certain situations. This communication is to determine the compliance risks to TEVA of continuing to do business, and if the customer is compliant with all applicable state and federal statutes and regulations.

6.2 Announced Site Visits

6.2.1 Announced site visits will be coordinated with Customer Account Management, and will be scheduled by, and conducted in conjunction with, a National Account Manager or designee.

6.2.2 Before the visit, DEA Compliance will determine the scope of the visit and what information will be requested of the customer. If necessary, details of the required information, including the scope, will be provided to the customer via Customer Account Management.

6.2.3 During the visit, DEA Compliance personnel will properly identify themselves and explain the scope and background for the visit.

6.2.4 DEA Compliance personnel will collect the following information:

- Pertinent demographic data
- Name and title of all participants
- Any and all information as predetermined by DEA Compliance

6.2.5 DEA Compliance personnel will complete a written report detailing all findings and listing required information that was requested as per 6.2.2. The written report will be maintained in the customer's DEA Compliance File.

SOP #:	<b>SOP- 8280</b>
TITLE:	SUSPICIOUS ORDER MONITORING – CUSTOMER SITE VISITS

6.2.6 Based on information gathered by DEA Compliance personnel during the visit, DEA Compliance will make a determination of what action, if any, needs to be taken, up to, and including the cessation of the sale of controlled substances and listed chemicals. Restrictions, if any, will be noted on the DNS as per SOP-8278.

**6.3 Announced Site Visit Refusal**

6.3.1 If it has been determined by DEA Compliance that a site visit is warranted, and the customer refuses an announced site visit with designated DEA Compliance personnel, sales of controlled substances and listed chemicals will be halted and the customer added to the DNS as per SOP-8278.

6.3.2 Any open orders for controlled substances for a customer who has refused an announced site visit, will be cancelled and reported as suspicious to the DEA as per SOP-8277.

**Customer Account Management**

6.3.3 Customer Account Management will inform the customer that all sales of controlled substances and listed chemicals will be halted due to the refusal of an announced site visit.

**6.4 Unannounced Site Visits**

6.4.1 Due to their sensitive nature, unannounced site visits will be conducted only at the direction of Legal. Unannounced site visits should be infrequent.

6.4.2 Details of the visit, including the method of visit, what materials are to be gathered during the visit, method of reporting etc., will be determined at the direction of Legal, and will be maintained as confidential.

6.4.4 Reports and findings of any unannounced site visit will be disseminated only at the discretion of Legal.

**7. ATTACHMENTS**

N/A

SOP #:	<b>SOP- 8280</b>
TITLE:	Suspicious Order Monitoring – Customer Site Visits

QUIZ

1. DEA Compliance will determine the scope of all site visits.  
TRUE or FALSE
2. All site visits will be scheduled by Customer Account Management.  
TRUE or FALSE
3. Final disposition from an announced site visit will be determined by DEA Compliance.  
TRUE or FALSE
4. A customer who refuses an announced site visit will continue to receive all orders.  
TRUE or FALSE

SIGNATURES

Employee (print name):	
Employee (signature):	Date:

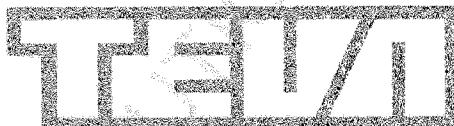
*Quiz answers checked for correctness. All questions incorrectly answered were discussed with the employee and understood.*

Instructor (signature):	Date:
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Employee (signature):	Date:

*Quiz answers checked for correctness. All questions incorrectly answered were discussed with the employee and understood.*

Instructor (signature):	Date:
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